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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,357

09/18/2006

Stefan Verseck

009848-0356700

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01/11/2010

PILLSBURY WINTHROP SHAW PITTMAN LLP

ATTENTION: DOCKETING DEPARTMENT

P.O BOX 10500

McLean, VA 22102

EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

01/11/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of SEQ ID NO: 72 and 84 in the reply filed on September 17, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The response was considered incomplete, as Applicants did not elect a SEQ ID NO for the α -subunit. Mr. Robert Bedgood informed examiner in a telephone message on December 7, 2009, that SEQ ID NO: 50 was intended to be elected for the α -subunit. Consequently, all three SEQ ID NOs were searched.
3. Claims 1-11 were previously pending, with claims 1-5, 7, 8, 10 and 11 withdrawn from consideration. Applicants amended claims 6 and 9 and added new claims 12-15. Claims 6, 9 and 12-15 will be examined to the extent that they read on SEQ ID NO: 50, 72 and 84.
4. Applicants' amendments overcame all of the previously presented rejections. This office action contains new grounds for rejection necessitated by amendment.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 6, 9 and 12-15 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph,

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A Written Description Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

The current claims are drawn to a protein sequence comprising SEQ ID NO: 50, SEQ ID NO: 72 or SEQ ID NO: 50, 72 and 84 or sequences 90% identical to these SEQ ID NOs, where the protein has nitrile hydratase activity.

Credible Utility

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of the proteins. The only cited utility

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identified by the examiner is the use of these proteins as nitrile hydratases. This utility is credible.

Upon identification of credible utilities, the next issue is whether there are any well established utilities for the protein. No well established utilities for the claimed protein are identified in the specification.

Substantial Utility

Given the absence of a well established utility, the next issue is whether substantial utilities are disclosed in the specification. The following evidence is presented by Applicants in the specification: amino acid sequences with SEQ ID NO: 50 and 72, which are allegedly α - and β -subunits of nitrile hydratases, were obtained by PCR amplification from metagenome libraries and cloning of the amplified fragments, the clones subsequently screened for nitrile hydratase activity (pages 21-26 of the specification). Only the following combination of subunits were shown to possess nitrile hydratase activity: SEQ ID NO: 49/71 (+ SEQ ID NO: 83), SEQ ID NO: 39/63; SEQ ID NO: 57/79 (+ SEQ ID NO: 85) and SEQ ID NO: 59/63 (page 24-26). There is no evidence that the combination of SEQ ID NO: 50 and 72 (with or without SEQ ID NO: 84) has nitrile hydratase activity.

Therefore a protein comprising SEQ ID NO: 50 and 72 lacks substantial utility, since further experimentation would be necessary to establish such a utility, i.e., the protein's function.

Specific Utility

In view of the above, the combination of SEQ ID NO: 50 and 72 also lacks any specific utility.

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Applicant should explicitly identify a specific and substantial utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

7. Claims 6, 9 and 12-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 6, 9 and 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a protein sequence comprising SEQ ID NO: 50, SEQ ID NO: 72 or SEQ ID NO: 50, 72 and 84 or sequences 90% identical to these SEQ ID NOs, where the protein has nitrile hydratase activity. However, Applicants did not show any evidence that a protein comprising the subunits with SEQ ID NO: 50 and 72, with or without SEQ ID NO: 84, possesses nitrile hydratase activity. Only the following combination of subunits were shown to

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possess nitrile hydratase activity: SEQ ID NO: 49/71 (+ SEQ ID NO: 83), SEQ ID NO: 39/63; SEQ ID NO: 57/79 (+ SEQ ID NO: 85) and SEQ ID NO: 59/63 (page 24-26).

Therefore, Applicants were not in possession of the claimed invention.

10. No references were found teaching or suggesting claims 6, 9 and 12-15, but they are rejected for reasons given above.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

/Teresa E Strzelecka/
Primary Examiner, Art Unit 1637
December 28, 2009